

Nathaniel L. Dilger (Cal. Bar No. 196203)

Email: ndilger@onellp.com

Joseph K. Liu (Cal. Bar No. 216227)

Email: jliu@onellp.com

**ONE LLP**

4000 MacArthur Blvd

East Tower, Suite 500

Newport Beach, CA 92660

Telephone: (949) 502-2870

Facsimile: (949) 258-5081

Peter L. Berger (*Admitted Pro Hac Vice*)

Email: pberger@llbl.com

Jonathan Andrew Berger (*Admitted Pro Hac Vice*)

Email: jberger@llbl.com

Tuvia Rotberg (*Admitted Pro Hac Vice*)

Email: trotberg@llbl.com

**LEVINSOHN BERGER LLP**

11 Broadway, Suite 615

New York, NY 10004

Telephone: (212) 486-7272

Facsimile: (212) 486-0323

Attorneys for Plaintiffs/Counter-Defendants

CDx Diagnostics, Inc. and

Shared Medical Resources. LLC

**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA**

CDX DIAGNOSTICS, INC., and  
SHARED MEDICAL RESOURCES, LLC,

Plaintiffs,

v.

HISTOLOGICS, LLC, POPLAR  
HEALTHCARE PLLC, MATTISON  
PATHOLOGY LLP, AND JOHN DOES 1-  
30,

Defendants.

AND RELATED COUNTERCLAIM

Case No. CV13-07909 DOC (RNBx)

**MEMORANDUM OF POINTS AND  
AUTHORITIES IN SUPPORT OF  
SHARED MEDICAL RESOURCES,  
LLC AND CDX DIAGNOSTICS,  
INC.'S MOTION TO DISMISS  
HISTOLOGICS, LLC'S  
INVALIDITY, INEQUITABLE  
CONDUCT, UNENFORCEABILITY  
AND FRAUD AFFIRMATIVE  
DEFENSES AND COUNTERCLAIMS**

Date: April 21, 2014

Time: 8:30 a.m.

Courtroom: 9D

1 **I. INTRODUCTION**

2 The doctrine of assignor estoppel precludes an assignor of a patent from later  
3 challenging the validity or enforceability of what the assignor previously sold. Here,  
4 Histologics and its principals are prior owners and inventors of the asserted '044 patent,  
5 including Neal Lonky, who is a principal of Histologics and a coinventor of the '044  
6 patent. The doctrine thus bars Histologics (and those in privity with it) from asserting  
7 invalidity or unenforceability as defenses or counterclaims.

8 Defendants, however, ignore this well-known doctrine and contend that, under 35  
9 U.S.C. Sec. 102(b), the '044 patent is valueless based on pre-filing activities of Neal Lonky  
10 while at a prior company, Trylon Corporation, which is a predecessor to Histologics.  
11 Importantly, Neal Lonky never told the Patent Office of such alleged infirmity when his  
12 inventor's declaration was submitted, nor thereafter did they inform any purchaser of the  
13 '044 patent of these infirmities. In this litigation, Histologics - in which Neal Lonky is a  
14 principal - seeks to undermine the '044 patent that Neal Lonky previously assigned. This is  
15 precisely the sort of back dealing that the doctrine of assignor estoppel precludes.

16 Additionally, Trylon received royalties from CDx of several hundred thousand  
17 dollars based on the '044 patent and Trylon used the '044 patent as valuable collateral for a  
18 loan that was purchased by plaintiff SMR. This further confirms that Histologics and Mr.  
19 Lonky - who are in privity with Trylon - should be barred from now challenging the  
20 validity and enforceability of the '044 patent.

21 The doctrine of assignor estoppel thus requires the dismissal of Histologics'  
22 affirmative defenses and counterclaims for invalidity and inequitable conduct under Rule  
23 12 of the Federal Rules of Civil Procedure.

24 **II. FACTUAL BACKGROUND**

25 **A. HISTORY OF THE '044 PATENT**

26 U.S. Patent No. 6,258,044 (or "the '044 patent") was filed on July 23, 1999, issued  
27 on July 10, 2001, and lists Neal M. Lonky and Jeremy Papadopoulos as inventors. (Exh.1,  
28

'044 Patent, Cover Page).<sup>1</sup> The '044 patent describes an apparatus and method for obtaining a transepithelial specimen of a body surface using a non-lacerational technique. The invention is directed to using a "transepithelial brush" with stiff bristles to collect tissue samples from below the top tissue layer for the purpose of conducting cancer screening, all without the need for any type of cutting surgical procedure.

The '044 patent was originally assigned by Lonky and Papadopoulos to the OralScan Laboratories, Inc. ("Oralscan") and then from Oralscan to The Trylon Company ("Trylon")(Exhibit 2: Reel/Frame 011929/0629, p. 1 of 5 - Assignment Abstract.) Neal Lonky signed a second assignment dated June 29, 2001. (Exh. 3- Lonky Assignments). Importantly, Trylon was founded by the '044 patent inventor, Neal M. Lonky, M.D., and his brother Martin Lonky. (Exh. 4, Declaration of Neal Lonky, M.D. ("Lonky Decl.," ¶¶ 4, 10). As explained further below, the '044 patent has changed hands several times since this original assignment, and is now held by Plaintiffs. (Declaration of Mark Rutenberg, ("Rutenberg Decl."), ¶3).

**B. THE PARTIES AND THEIR RELEVANT PREDECESSORS**

**1. Plaintiff Shared Medical Resources.** SMR is a Delaware limited liability company located in Newport Beach, California. Trylon entered into a loan agreement and pledged all of its assets, including the '044 patent, as collateral for a loan obtained from Pacific Republic Capital, LLC ("PRC"). (Declaration of Dan Olsen ("Olsen Decl."), ¶3). Trylon defaulted on the loan, and PRC started foreclosure. SMR acquired the defaulted loan from PRC, resulting in SMR acquiring the '044 patent from Trylon through foreclosure of Trylon's loan. (Olsen Decl.), ¶2). SMR currently offers for sale and sells medical products, including a brush called the SpiraBrush CX, to laboratories and clinicians for use in cervical biopsies. (Olsen Decl., ¶3).

**2. Plaintiff CDx Diagnostics.** CDX, whose predecessor was Oralscan Inc. ("Oralscan"), is a Delaware corporation located in Suffern, New York. CDX specializes in

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<sup>1</sup> Unless stated otherwise, all exhibits are attached to the accompanying Declaration of Peter L. Berger ("Berger Decl.").

research and development in the field of analyzing cellular samples for dysplasia in epithelial tissue. (Rutenberg Decl., ¶2). On or about April 18, 2006, OralScan Laboratories, Inc., which is now CDX, paid the then-owner of the '044 patent, plaintiff SMR, approximately \$350,000.00 to acquire an equal and undivided joint interest in the '044 Patent that SMR had obtained from Trylon. (Rutenberg Decl., ¶7)

**3. Trylon Corporation.** Prior to forming Defendant Histologics, Neal and Martin Lonky formed The Trylon Company. (Exh. 3., Lonky Decl., ¶¶ 4. 10). Neal Lonky and the other named co-inventor assigned their interests in the '044 patent to Oralscan (now Plaintiff CDx). (Exh. 3-Lonky Assignments and Exh. 4- Papadopoulos Assignment). Oralscan later assigned the '044 Patent to Trylon. During Trylon's ownership of the '044 Patent, Oralscan was a licensee thereof and it paid about \$200,000 in license fees to Trylon. ("Rutenberg Decl."), ¶10). Oralscan submitted to the Patent Office an inventor declaration with Neal Lonky's signature as well as an assignment signed by Neal Lonky assigning the patent application to the Oralscan. (Exh. 3, Lonky Assignments and Exh.8 – Lonky Assignor Declaration). In May 2005, the '044 Patent, among other Trylon assets, was transferred to SMR as a result of Trylon's default on a loan agreement. (Olsen Decl., ¶3) After defaulting on the Trylon loan, the Lonky brothers formed Defendant Histologics. (Exh. 5, Lonky Decl., ¶¶3-6), and began selling biopsy brushes covered by the '044 patent.

**4. Defendant Histologics LLC.** Histologics is located in Yorba Linda, California, and was founded in 2008 by Neal Lonky and Martin Lonky. (Exh 5, Lonky Decl., ¶¶3-6) Neal Lonky is a founder (Exh 6, Histologics About-Us Page), and managing member and a Director of Histologics (Exh 5, Lonky Decl., ¶2). Histologics markets and sells products identified as Soft-ECC and Soft-Biopsy. (Exh 5, Lonky Decl., ¶6) which Plaintiffs allege infringes the '044 Patent.

Despite their earlier assignment of the '044 patent and the value they received as a result of that patent, Histologics and the Lonkys now assert that the '044 Patent was never valid and was void *ab initio* because of prior sales activities of the Lonkys while at Trylon.

(Exh. 7, (Dkt. 111) and (Dkt. 112) (“First Amended Answer and Counterclaim”), e.g., ¶¶94-97, Count 2)).

### III. ARGUMENT

#### A. ASSIGNOR ESTOPPEL

Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or patent application) from later contending that what was assigned is a nullity. *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224 (Fed Cir. 1988), *cert. dismissed*, 487 U.S. 1265 (1988); *see also Shamrock Tech., Inc. v. Medical Sterilization, Inc.*, 903 F.2d 789 (Fed. Cir., 1990); *Q.G. Products, Inc. v. Shorty, Inc.*, 992 F.2d 1211 (Fed. Cir. 1993). The Federal Circuit, in explaining the rationale for the assignor estoppel doctrine, stated that “[i]t is the implicit representation by the assignor that the patent rights that he is assigning (presumably for value) are not worthless that sets the assignor apart from the rest of the world and can deprive him of the ability to challenge later the validity of the patent. To allow the assignor to make that representation at the time of the assignment (to his advantage) and later repudiate it (again to his advantage) could work an injustice against the assignee.” *Diamond*, 848 F.2d at 1224.

Assignor estoppel also operates to bar not only the original assignor, but any party in privity with the assignor, such as a corporation founded by the assignor. *Diamond*, 848 F.2d at 1224. “Those in privity with the assignor partake of that balance; hence, extension of the estoppel to those in privity is justified.” *Shamrock Tech.* 903 F.2d at 793; *see also Diamond*, 848 F.2d at 1224. Privity may be established where there is a close relationship among the relevant parties, for example, where the ultimate infringer availed itself of the inventor’s knowledge and assistance to conduct infringement. *Intel Corp. v. United States International Trade Commission*, 946 F.2d 821, 839 (Fed Cir. 1991) (citations omitted). Thus, “if an inventor assigns his invention to his employer company A and leaves to join company B, whether company B is in privity and thus bound by the doctrine will depend on the equities dictated by the relationship between the inventor and company B in light of

1 the act of infringement. The closer that relationship, the more the equities will favor  
2 applying the doctrine to company B.” *Shamrock Tech.*, 903 F.2d at 793.

3 **B. ASSIGNOR ESTOPPEL APPLIES TO NEAL LONKY**

4 Neal Lonky is an inventor of the ‘044 patent. (Exh.1, ‘044 Patent, Cover Page).  
5 After OralScan and Trylon entered into their joint venture, Neal Lonky then assigned the  
6 “entire right, title and interest” to the claimed invention to OralScan in July, 1999. (Exhibit  
7 3, Neal Lonky Assignment documents). In addition, Trylon submitted an inventor  
8 declaration bearing Neal Lonky’s signature, stating he was an inventor of the claimed  
9 subject matter and was unaware of anything that would prevent a patent from being  
10 granted. (Exhibit 8, Lonky Inventor Declaration).

11 Because Neal Lonky assigned all of his right, title and interest to the claimed  
12 invention, Neal Lonky is barred from asserting invalidity of the ‘044 patent. Otherwise,  
13 “[t]o allow the assignor to make that representation at the *time of the assignment (to his*  
14 *advantage) and later repudiate it (again to his advantage) could work an injustice against*  
15 *the assignee.”* *Diamond*, 848 F.2d at 1224 (emphasis added).

16 **C. ASSIGNOR ESTOPPEL APPLIES TO HISTOLOGICS**

17 Neal Lonky is one of the founders (Exh. 6, Histologics website) and a managing  
18 member and director of Defendant Histologics LLC. (Exh. 5, Lonky Decl., ¶2).  
19 Histologics is also availing itself of Neal Lonky’s purported knowledge of invalidity to  
20 conduct and justify its infringing activities. *See Intel Corp.*, 946 F.2d at 839.

21 In *Diamond Scientific Co. v. Ambico, Inc.*, Appellee Diamond Scientific Co.  
22 (“Diamond”) employed Dr. Clarence Welter. During that time, Dr. Welter invented and  
23 filed a patent application for a vaccine designed to address gastroenteritis in swine. During  
24 the patent application process, Dr. Welter assigned all of his rights to Appellee Diamond.  
25 After Dr. Welter left Diamond, he formed Appellant Ambico Inc. and became the vice  
26 president. Shortly thereafter, Ambico was accused of patent infringement following the  
27 manufacture and sale of its own gastroenteritis swine vaccine. *Diamond*, 848 F.2d at 1224.



1 The Federal Circuit upheld the lower court's decision to apply assignor estoppel to  
2 Ambico in finding that, "[w]hen the inventor-assignor has signed the Oath, Power of  
3 Attorney and Petition, which attests to his belief in the validity of the patents, and has  
4 assigned the patent rights to another for valuable consideration, he should be estopped from  
5 defending patent infringement claims by proving that what he assigned was worthless.  
6 That is an implicit component of the assignment by Welter to Diamond which is immune  
7 from contradiction." *Id.* at 1225–26. The Court emphasized

8 Our concern must be the balance of the equities. The fact is that Dr. Welter  
9 assigned the rights to his invention, irrespective of the particular language in  
10 the claims describing the inventions when the patents were ultimately  
11 granted. Appellants should not be allowed now to destroy those rights by  
12 derogating the patents' validity.

13 *Id.* at. 1226.

14 Assignor estoppel applies in this case. First, as an inventor and assignor of the '044  
15 patent, Neal Lonky is precluded from asserting that the patent is and always has been  
16 invalid (Exh. 3- Lonky assignments and Exh.8 –Lonky inventor declaration). As in  
17 *Diamond*, Neal Lonky attested to his belief in the validity of the '044 patent and assigned  
18 his rights to another for valuable consideration. (Exh. 3- Lonky assignments and Exh.8 –  
19 Lonky inventor declaration). Otherwise, "[t]o allow the assignor to make that  
20 representation at the *time of the assignment (to his advantage) and later repudiate it (again*  
21 *to his advantage)* could work an injustice against the assignee." *Diamond*, 848 F.2d at  
22 1224 (emphasis added).

23 Second, the doctrine of assignor estoppel applies to Histologics because it is in  
24 privity with Dr. Lonky. *Diamond*, 848 F.2d at 1224 ("The estoppel also operates to bar  
25 other parties in privity with the assignor, such as a corporation founded by the assignor.")  
26 In this matter, Histologics was founded and is managed by Dr. Lonky and his brother, just  
27 like Trylon, before Histologics, and therefore shares privity with an assignor alleging patent  
28 invalidity. (Exh 5, Lonky Decl., ¶¶3-6). Also, Histologics is availing itself of Dr. Lonky's

1 purported knowledge of invalidity to conduct and justify its infringing activities. *See Intel*  
2 *Corp.*, 946 F.2d at 839.

3 There is likewise privity between Trylon and Histologics. Specifically, Trylon -  
4 which owned the Asserted Patent for several years prior to the assignment to SMR - was  
5 formed by Neal and Martin Lonky. And after Trylon's bankruptcy, Neal and Martin Lonky  
6 went on to form Histologics. This further confirms that privity applies also to Histologics.  
7 *Diamond*, 848 F.2d at 1224; *Shamrock Tech.*, 903 F.2d at 793.

8 Based on the foregoing, this Court should bar Defendant Histologics from asserting  
9 patent invalidity claims on the basis of assignor estoppel. For the same exact reason as  
10 explained in *Diamond Scientific*, Histologics and Dr. Lonky should not be allowed to  
11 destroy those rights by derogating the '044 patent's validity because "[T]o allow the  
12 assignor to make that representation at the time of the assignment (to his advantage) and  
13 later repudiate it (again to his advantage) could work an injustice against the assignee."  
14 *Diamond*, 848 F.2d at 1224.

15 **D. ASSIGNOR ESTOPPEL LIKEWISE BARS ANY CLAIM OF INEQUITABLE**  
16 **CONDUCT**

17 Assignor estoppel not only acts with respect to a challenge to patent validity but also  
18 acts as a bar with respect to a claim of inequitable conduct. *See Shamrock Tech.*, 903 F.2d  
19 789, 793. The Federal Circuit Court explained that:

20 It is at best incongruous to suppose that the equitable doctrine of assignor  
21 estoppel can never be applied to an equitable defense. The premise of the  
22 doctrine, prevention of unfairness and injustice, is not removed upon the  
23 mere denomination of a defense as 'equitable'.... If we were to hold  
24 otherwise, *Diamond Scientific* could be avoided by merely couching  
25 invalidity defenses in terms of inequitable conduct . . .

26 *Id.* at 794-795

27 Assignor estoppel applies here to bar the equitable defense of inequitable conduct not  
28 only because of Neal Lonky's signed inventor/assignor declaration but also due to Mr.  
Lonky's silence for many years while enjoying the benefits of owning the '044 Patent



1 including the licensing fees paid by OralScan/CDx and the loan obtained from SMR (Exh.  
2 2, Reel/Frame 017353/0931, p. 2 of 5, Abstract).

3 Furthermore, it is generally irrelevant that events relating to invalidity ordinarily  
4 occur before the inventor signs the declaration when he is in position to know and control  
5 them, whereas acts constituting inequitable conduct ordinarily occur after the inventor signs  
6 the declaration. *Shamrock Tech.*, 903 F.2d at 795.

7 In *Shamrock Technologies*, the Federal Circuit barred the inequitable conduct  
8 defense for several reasons. First, Appellant made allegations as to misconduct on the part  
9 of Appellee during the patent prosecution process. However, the Federal Circuit upheld the  
10 lower court's basis because the district court correctly determined that those allegations  
11 directly contradict statements made by the inventor in the inventor's declarations. *Id.*  
12 Second, the assignor tried to distinguish invalidity and inequitable conduct defenses on the  
13 ground that "events relating to invalidity ordinarily occur before the inventor signs the  
14 declaration when he is in position to know and control them, whereas acts constituting  
15 inequitable conduct ordinarily occur after the inventor signs the declaration." *Id.* The  
16 Federal Circuit disagreed with this position because "the basis for a defense arises after the  
17 inventor has signed a declaration . . . is ordinarily irrelevant, the inventor having assigned  
18 the rights to his invention, not alone to a patent application." *Id.*

19 The Federal Circuit did state that in a proper case, general principles of equity may  
20 preclude use of assignor estoppel to bar a viable equitable defense arising from post-  
21 assignment events, but such exception clearly does not apply in the case at hand. In this  
22 case, the First Amended Answer and Corrected Counterclaims essentially allege that the  
23 invention was in public use or on sale at least one year prior to the application. (Exh 7, First  
24 Amended Answer and Counterclaims, see e.g. ¶74). But Neal Lonky's inventor/assignor  
25 declaration names Neal Lonky along with Jeremy James Michael Papadopoulos as joint  
26 inventors and contains Neal Lonky's signature. (Exh. 3- assignments and Exh.8 –inventor  
27 declaration). Notably, Neal Lonky's declaration clearly states that the invention was not in  
28 public use or on sale in the United States . . . more than one year prior to the application for

1 the '044 patent. *Id.* Hence, the declaration flatly contradicts the allegations set forth in  
2 Defendant Histologics' Answer and Corrected Counterclaims.

3 In addition, after the '044 Patent was issued, OralScan/CDx assigned it to Trylon in  
4 2001 as required by the OralScan/Trylon licensing agreement. (Exh. 2: Reel/Frame  
5 011929/0629, Abstract, p. 2 of 5). Neither Trylon nor Lonky raised any issues then  
6 concerning validity or inequitable conduct. The '044 Patent next changed ownership in  
7 2005 when it was transferred to SMR. (Exh. 2, Reel/Frame 017353/0931, Abstract, p. 2 of  
8 5). Trylon owned the Asserted Patent for approximately four years after acquiring  
9 ownership from OralScan/CDx. If the '044 Patent should never have been issued, then  
10 Trylon and/or Lonky were obligated to report this to the United States Patent Office as  
11 required by the inventor/assignor declaration. (Exh. 7, First Amended Answer and  
12 Counterclaims, see e.g. ¶74)

13 As in the *Shamrock Technologies* case, the allegations made in Defendant  
14 Histologics' Answer and Corrected Counterclaims in support of its inequitable conduct  
15 defense are not only directly contradicted by the assignor-inventor declaration but also by  
16 the assignor's conduct and Histologics' claims with respect to inequitable conduct should  
17 be dismissed. The doctrine of assignor estoppel squarely precludes assignors from making  
18 such an about-face.

#### 19 **IV. CONCLUSION**

20 Based on the foregoing, Plaintiff's SMR and CDx respectfully request that the Court  
21 grant their Motion to Dismiss Defendant Histologics' affirmative defenses and  
22 counterclaims for invalidity and inequitable conduct under Rule 12(c) of the Federal Rules  
23 of Civil Procedure.

24  
25 Dated: March 21, 2014

**ONE LLP**

26  
27 By: /s/ Nathaniel Dilger  
Nathaniel L. Dilger, Esq.  
28 *and*

**LEVISOHN BERGER LLP**

By: /s/ Peter Berger  
Peter L. Berger (*Pro Hac Vice*)

*Attorneys for Plaintiffs and Counter-Defendants,  
CDx Diagnostics, Inc. and  
Shared Medical Resources, LLC*